



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2648]

Announcement of Requirements and Registration for the 2016 Food and Drug Administration

Naloxone App Competition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the 2016 FDA Naloxone App Competition (Competition), a prize competition under the America COMPETES Reauthorization Act of 2010 (COMPETES Act). The Competition is an effort to help reduce deaths associated with prescription opioid and heroin overdose by seeking innovative approaches to help reduce preventable harm associated with opioids. Specifically, the goal of this Competition is to spur innovation around the development of a low-cost, scalable, crowd-sourced mobile phone application that helps increase the likelihood that opioid users, their immediate personal networks, and first responders are able to identify and react to an overdose by administering naloxone, a medication that reverses the effects of opioid overdose.

DATES: The Competition begins [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

1. Registration for the Competition: September 23 to October 7, 2016
2. Naloxone App Code-a-Thon: October 19 and October 20, 2016
3. Submission Period: September 23 to November 7, 2016

FOR FURTHER INFORMATION CONTACT: Marisa Cruz at naloxoneapp@fda.hhs.gov, or 240-402-6628.

SUPPLEMENTARY INFORMATION:

I. Background

In 2014, nearly 2 million Americans aged 12 years or older either abused or were dependent on opioid painkillers (Ref. 1). In 2014, 61 percent of drug overdose deaths involved either an opioid painkiller or heroin. Between 2013 and 2014, deaths from any opioid increased 14 percent (Ref. 2). Naloxone is an antidote for an opioid overdose, whether from prescription opioids or heroin. It is a prescription drug, with generally minimal side effects, that is frequently used to reverse the effects of opioid overdose in emergency rooms and on ambulances. Over recent years, many States have taken steps to make it easier for both first responders and laypersons, including family and friends of opioid users, to carry and administer naloxone (Ref. 3).

Even with naloxone increasingly available in the community, however, persons carrying naloxone may not be on hand when an opioid overdose occurs. There is still the practical need to connect the individual experiencing the opioid overdose quickly and effectively with an individual carrying naloxone. Mobile phone applications (apps) have been developed to educate laypersons on opioid overdose and administration of naloxone (Refs. 4 and 5), and to connect bystanders with individuals in need of other medical services (Ref. 6). In a randomized, controlled trial, researchers demonstrated that a mobile-phone positioning system to dispatch laypersons trained in cardiopulmonary resuscitation (CPR) was associated with significantly increased numbers of bystander-initiated CPR procedures on persons with out-of-hospital cardiac

arrest (Ref. 7). To date, however, we are not aware of an app that has been developed to connect carriers of naloxone with nearby opioid overdose victims.

II. Subject of Competition

The Competition encourages computer programmers, public health advocates, clinical researchers, entrepreneurs, and innovators from all disciplines to create teams focused on the development of innovative strategies to combat the rising epidemic of opioid overdose. Specifically, the Competition invites submissions for an app that increases the likelihood of timely naloxone administration by connecting opioid users experiencing an overdose with nearby naloxone carriers. FDA is most interested in concepts that are readily scalable, free or low-cost to the end-user, and take advantage of existing systems for naloxone distribution and use. FDA's expectation is that any app developed through the Competition will be used with FDA-approved naloxone products. For additional background information on the Competition, participants can access <http://www.Challenge.gov>.

Interested parties may register for the Competition at <http://www.Challenge.gov> beginning on September 23, 2016; participants are highly encouraged to register as teams, but individual applicants will also be accepted. The Competition will be conducted in two phases. Phase 1 will consist of a code-a-thon hosted at the FDA campus in Silver Spring, Maryland, for registered entrants to develop their concepts and initial prototypes for an app that alerts carriers of naloxone to a nearby opioid overdose. Entrants are encouraged, but not required, to participate in the code-a-thon. The code-a-thon will occur on October 19 and October 20, 2016. All code developed through the code-a-thon will be made open-source and publicly accessible on the GitHub platform, a Web-based code repository. The code-a-thon event space is limited to the first 50 individuals who indicate interest in onsite participation during the registration process.

(see Section IV). There will be a virtual component to the code-a-thon for the first 100 individuals who indicate interest in remote participation during the registration process. In Phase 2, all registered entrants will refine their concepts and develop a functional prototype, a video of which will be submitted on <http://www.YouTube.com> by the submission deadline. The video will be accompanied by a short summary of the prototype, as detailed in this document, which will be submitted on <http://www.Challenge.gov>.

Federal Agency subject matter experts will provide background and technical information to entrants on topics including, but not limited to, the opioid epidemic, uses of approved formulations of naloxone, and regulatory science considerations. During all phases of app development, all entrants should consider strategies to minimize legal risk and maximize regulatory compliance, including for the developer and the end-user. To ensure adequate consideration of potential liability, privacy, and regulatory concerns, FDA strongly encourages all entrants to obtain independent legal counsel.

FDA is sponsoring the Competition and will be providing entrants with technical expertise from the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA). Specifically, NIDA and SAMHSA will each provide one judge with experience in relevant fields including drug use and misuse, clinical trial design, development of mobile medical applications, and public health. Additionally, NIDA and SAMHSA will provide information to Competition entrants at the code-a-thon on key issues, including (1) patterns of opioid use and misuse, (2) characteristics of populations at risk of opioid overdose, and (3) data collection and evaluation considerations.

Entrants may not test or evaluate their app using real people, including opioid users and naloxone carriers, during the Competition. Following the Competition, entrants may consider

seeking grant funding from the NIDA Small Business Innovation Research (SBIR) program to further develop and bring to scale Competition concepts through testing and evaluation. As with all other National Institutes of Health (NIH) funding applications, NIDA staff will provide dedicated assistance and guidance about the NIH grant submission process, including submissions for the NIDA SBIR grants. The SBIR grant program is open to all small businesses (which may include Competition entrants) that meet applicable eligibility requirements set forth in the SBIR funding opportunity announcement. More information is available at <http://grants.nih.gov/grants/guide/pa-files/PA-16-302.html>. For Competition entrants and projects that meet all applicable SBIR requirements, the NIDA SBIR program may provide the opportunity to further develop Competition concepts through field testing and evaluation.

The primary goal of the Competition is to reduce death from opioid overdoses by expanding access to naloxone, in support of the Federal Government's mission to protect and advance public health. The secondary goals of the Competition are:

- To increase public awareness about naloxone and its role in reducing death from opioid overdoses; and
- To promote open government and citizen participation to improve innovation in the Federal Government.

III. Eligibility Rules for Participating in the Competition

To be eligible to win a prize under this Competition, an entrant (individual or entity):

- Shall have registered and entered a submission on <http://www.Challenge.gov> and <http://www.YouTube.com> under the rules promulgated by FDA;
- Shall have complied with all the requirements under this section;

- Shall be (1) an individual or team of U.S. citizens or lawful permanent residents of the United States, each of whom is 18 years of age and over; or (2) an entity incorporated in and maintaining a primary place of business in the United States. Foreign citizens can participate as employees of an entity that is properly incorporated in the United States and maintains a primary place of business in the United States;
- May not be a Federal entity or Federal employee acting within the scope of their employment. An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.
- Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award. Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.
- Employees of FDA, NIDA, SAMHSA, and/or any other individual or entity associated with the development, evaluation, or administration of the Competition as well as members of such persons' immediate families (spouses, children, siblings, parents), and persons living in the same household as such persons, whether or not related, are not eligible to participate in the Competition.
- Entrants must agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or

consequential, arising from their participation in the Competition, whether the injury, death, damage, or loss arises through negligence or otherwise.

- Entrants must also agree to indemnify the Federal Government against third party claims for damages arising from or related to competition activities. Entrants are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in the Competition.
- By participating in the Competition, each entrant agrees to comply with and abide by the rules of the Competition and the decisions of FDA and/or the individual judges, which shall be final and binding in all respects.
- Each entrant agrees to follow all applicable local, State, and Federal laws and regulations.

IV. Registration Process for Participants

Registration for this Competition will open on September 23, 2016. To register, visit <http://www.Challenge.gov>, search for the 2016 FDA Naloxone App Competition, and follow the instructions. Entrants will receive an email confirming registration and participation in the code-a-thon, if applicable.

V. Submission Requirements

All written, digital, or recorded materials must be in English.

Submissions are required to include:

1. A video of the functional app prototype, not more than 5 minutes in duration, uploaded to <http://www.YouTube.com>; and
2. A written summary of the app, not to exceed three pages, submitted on <http://www.Challenge.gov>. This document should detail:
 - A description of the entrant(s), including relevant fields of expertise;

- A summary of the concept for the app, including identification of the target audience;
- A general description of the proposed technical design, including an explanation of any planned interfaces between the app and existing systems or datasets; and
- The URL for the uploaded YouTube video.

To submit the written summary of the app, visit <http://www.Challenge.gov>, search for the 2016 FDA Naloxone App Competition, click on Submit Solution, and follow the instructions. For additional detail on required components of a submission, and the minimum requirements for the proposed app, participants may access the rules for the Competition posted at <http://www.Challenge.gov>.

VI. Amount of the Prize

At the conclusion of judging after Phase 2 of the Competition, the highest-scoring entrant will receive an award of \$40,000.

The award approving official for this Competition is the FDA Associate Commissioner for Public Health Strategy and Analysis (Peter Lurie). Following the Competition, all entrants eligible for SBIR grants may also apply for a NIDA SBIR award, as announced in the NIH SBIR funding opportunity announcement, in order to research, develop, and evaluate app performance and utility.

VII. Payment of the Prize

The prize awarded under this competition will be paid by electronic funds transfer and may be subject to Federal income taxes. FDA will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

VIII. Basis Upon Which Winner Will Be Selected

A panel of judges with experience in the fields of mobile medical application development, public health, and/or regulatory science chosen by FDA will select the highest-performing entrant from the pool of eligible submissions.

Judging of eligible submissions will be fair and impartial, and based upon the following evaluation criteria, with equal weighting.

- Innovation: Uniqueness and innovation in use of software and data analytics to fulfill the mandatory requirements; variety and value of additional features (weight 25 percent).
- Usability: Use of design elements to increase utilization among both people at risk of opioid overdose and naloxone carriers; ease of navigation; appropriate use of an interface to support the app in achieving desired outcome (weight 25 percent).
- Functionality: Potential to enhance the frequency and speed of naloxone administration by the carriers to the overdose victims (weight 25 percent).
- Adaptability: Potential for app to be tailored to the practical environment (e.g., urban, rural) of an individual community (weight 25 percent).

IX. Additional Information

FDA reserves the right to suspend, postpone, terminate, or otherwise modify the Competition, or any entrant's participation in the Competition, at any time at the discretion of the Agency. FDA also reserves the right to not award a prize if no submission is deemed worthy. All decisions by FDA regarding adherence to Competition rules are final.

To receive the prize, entrants will not be required to transfer their intellectual property rights to FDA. Each entrant retains any applicable intellectual property rights to their submission. By participating in the Competition, each entrant hereby grants to FDA, and any third-parties acting on FDA's behalf an irrevocable, paid up, non-exclusive, royalty-free,

worldwide license and right to reproduce, publicly perform, publicly display, and use the entrant's submission for government purposes, and to publicly perform and publicly display the entrant's submission video, including, without limitation, for advertising and promotional purposes relating to the Competition.

Additionally, each participant at the code-a-thon will be required to provide FDA with an open source version of the code written by the participant at the code-a-thon to be posted on the GitHub source code repository and made publicly available under the Creative Commons license, CCO 1.0 Universal (CCO 1.0, Public Domain Dedication). For a summary and full text of the CCO 1.0 Universal license, see <https://creativecommons.org/publicdomain/zero/1.0/>. The GitHub source code repository is accessible at <https://github.com>.

X. Statutory Authority to Conduct the Challenge

FDA is conducting this Challenge under section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111-358).

XI. References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. Centers for Disease Control and Prevention. "Prescription Drug Overdose Data." Accessed September 9, 2016, at <http://www.cdc.gov/drugoverdose/data/overdose.html>.

2. Rudd, R.A., N. Aleshire, J.E. Zibbell, and R.M. Gladden. "Increases in Drug and Opioid Overdose Deaths--United States, 2000-2014." Morbidity and Mortality Weekly Report, 2015;64: 1-5. Accessed September 9, 2016, at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm64e1218a1.htm>.
3. Network for Public Health Law. "Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws." Accessed September 9, 2016, at https://www.networkforphl.org/_asset/qz5pvn/network-naloxone-10-4.pdf.
4. Substance Abuse and Mental Health Services Administration. "Opioid Overdose Prevention Toolkit." Accessed September 9, 2016, at <http://www.samhsa.gov/capt/tools-learning-resources/opioid-overdose-prevention-toolkit>.
5. U-turn. <http://www.u-turntraining.com/apps/>. Accessed September 9, 2016.
6. PulsePoint. <http://www.pulsepoint.org>. Accessed September 9, 2016.
7. Ringh, M., M. Rosenqvist, J. Hollenberg, et al. "Mobile-Phone Dispatch of Laypersons for CPR in Out-of-Hospital Cardiac Arrest." New England Journal of Medicine, 2015; 372:2316-2325.

Dated: September 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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